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501(k) Summary

DEC 21 2010

SUBMITTER NAME:	Ascension Orthopedics, Inc. 8700 Cameron Road, #100 Austin, TX 78754-3832
510(k) CONTACT:	Susan Walton Phone: (512) 836-5001 x1591
TRADE NAME:	Ascension® MOVEMENT Great Toe System
COMMON NAME:	prosthesis, toe (metatarso-phalangeal), joint, metal/polymer, semi-constrained
CLASSIFICATION:	unclassified
PRODUCT CODE:	LZJ
PANEL:	Orthopedic
PREDICATE DEVICES:	KGTI™ Kinetik Great Toe Implant System, Integra Lifesciences, K924724 Merete ToeMobile™ Anatomical Great Toe Resurfacing System, Merete Medical, K072251
DEVICE DESCRIPTION:	The Ascension® MOVEMENT Great Toe System, Total Arthroplasty device is an anatomically designed, semi-constrained, two-piece device designed for resurfacing of the base of the 1st metatarso-phalangeal (MTP) joint. The device couples with the Ascension metatarsal hemi-arthroplasty device to allow total arthroplasty of the 1st MTP joint. The device is designed for cemented fixation. The device is boxed individually and delivered sterile for single use. The device incorporates four anatomically designed base geometries with appropriately sized stems. The stem is cylindrical with tapered ribs to provide rotational as well as axial stability of the seated implant. System instrumentation is designed to offer precise implant preparation.

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INTENDED USE:

The Ascension® MOVEMENT™ Great Toe System, Total Arthroplasty is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only. Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallux rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

BASIS OF SUBSTANTIAL EQUIVALENCE:

Substantial equivalence was based upon testing and a geometrical comparison of the subject and predicate devices. Interconnection strength testing, axial, shear and bending strength, was performed to substantiate equivalence. Geometrical comparisons between the subject device, Ascension® MOVEMENT™ Great Toe System and Integra KGTI™ Kinetik Great Toe Implant System (K904724) were completed. The Merete ToeMobile™ Anatomical Great Toe Resurfacing System (K072251) was used as a template for labeled indications.

There are no significant differences between the Ascension MOVEMENT Great Toe System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 21 2010

Ascension Orthopedics, Inc.
% Ms. Susan Walton
8700 Cameron Road, #100
Austin, TX 78754-3832

Re: K102549
Trade/Device Name: Ascension MOVEMENT Great Toe System
Regulation Number: Unclassified
Regulation Name: Prosthesis, Toe (metatarso-phalangeal), Joint, Metal/polymer, Semi-constrained
Regulatory Class: Unclassified
Product Code: LZJ
Dated: December 9, 2010
Received: December 10, 2010

Dear Ms. Walton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number: K102549

Device Name: Ascension® MOVEMENT™ Great Toe System

Indications for Use:

The Ascension® MOVEMENT™ Great Toe System, Total Arthroplasty is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only. Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallux rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

Prescription Use ___X___ (Part 21 CFR 801Subpart B) OR Over-The-Counter Use _____ (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102549